Remarks

Preliminary Remarks

Claims 15-16 and 27-30 have been canceled because they are drawn to non-elected subject matter in accordance with the restriction requirement.

35 U.S.C. §112, First Paragraph

Claims 1-12, 17-18 and 26 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly the specification does not provide enablement for other growth hormone secretagogues.

Applicant respectfully asserts that the presently claimed invention, which relates to methods of intermittently administering a growth hormone secretagogue to a patient, is enabled because one skilled in the art can make and use the claimed invention without undue experimentation.

First, it is alleged that there is no definition of a growth hormone secretagogue. Applicant respectfully points the Examiner to page 9, lines 26-28 where the definition of the term growth hormone secretagogue is set forth. Moreover, how to determine if a compound is a growth hormone secretagogue is presented immediately after the definition of the term at page 9, lines 28-32. Those skilled in the art are familiar with growth hormone secretagogues, and it is routine in the art to determine whether a compound increases the secretion of growth hormone using routine testing. To illustrate, WO 97/24369, which has been cited in the Office Action in a subsequent 35 U.S.C. § 103 rejection, contains an *in vitro* assay starting at page 42, line23 and an *in vivo* assay is disclosed at page 44, line 1.

Because growth hormone secretagogues and assays for testing compounds to identify growth hormone secretagogues were well known to those in the art, the preset claimed invention, which is a method, is enabled because undue experimentation is not required. Instead, all that is required is simple, routine and well known experimentation to determine if a compound is a growth

hormone secretagogue. In view of the remarks above, Applicant respectfully requests withdrawal of this rejection.

35 U.S.C. § 103(a)

Claims 1-14 and 17-26 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over WO 97/24369.

Applicant respectfully submits that the presently claimed invention is patentable over WO 97/24369 because nowhere in WO 97/24369 is it taught or suggested that a growth hormone secretagogue could be administered intermittently.

It would not have been obvious to one skilled in the art at the time the invention was made to administer a growth hormone secretagogue intermittently because there would be no motivation administer a growth hormone secretagogue intermittently. Instead, most pharmaceutical compounds are administered daily. Daily administration is generally preferred because a therapeutically effective plasma level of a compound must be obtained and then maintained over time to obtain the desired therapeutic effect. Moreover, daily administration is typically preferred due to patient compliance. If intermittent administration is employed, patients can forget to take doses because a daily routine has not been established. Therefore, there would not have been motivation for one skilled in the art to employ intermittent administration of a growth hormone secretagogue.

Moreover, it has unexpectedly been found that higher plasma concentrations of growth hormone can be obtained using intermittent administration instead if daily administration (specification, page 6, lines 16-21; See also the human clinical trial and results set forth starting at page 63). Because one skilled in the art would not be motivated to administer a growth hormone secretagogue intermittently and because the intermittent administration provides for surprising and unexpected results with respect to plasma concentrations of growth hormone, the presently claimed invention is not obvious

in view of WO 97/243689. Applicant respectfully requests withdrawal of this rejection.

In view of the amendments and remarks made above, Applicant believes that claims 1-14 and 17-26 are in condition for allowance. Reconsideration and allowance of claims 1-14 and 17-26 is respectfully requested.

Respectfully submitted,

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